Application/Control Number: 10/600,006

Art Unit: 1616

Applicant and the assignee of this application are **required under 37 CFR 1.105 to provide the following information** that the examiner has determined is reasonably necessary to the examination of this application.

In the latest IDS of 7/23/2009, applicant submitted this document -

 LIN et al., "Experimental Results: Efficacy of AXENOHOL Solution in Eradicating Legionella pneumophilal," Special Pathogens Laboratory, VA Pittsburgh Healthcare System, Pittsburgh, PA 15240

A review of the document shows it to be particularly relevant because it discloses applicant's commercial product, AXENOHL. According to this document, it appears that AXENOHL was disclosed at the Third Asian Pacific Congress on Antisepsis, which was held in Sydney from January 24 to January 26, 1997.

Such a disclosure date <u>may</u> constitute a 102(b) date/disclosure against the instant application for the following reasons. Instant claims require presence of greater than 5% wt/vol citric acid, but such feature was not disclosed in the provisional application 60/061673. Consequently, the earliest effective filing date the instant claims <u>could</u> obtain is 10/9/1998, the filing date of grandparent application 09/169,229, which is more than one year after the meeting dates of Third Asian Pacific Congress on Antisepsis. Therefore, additional information is required to examine this application.

In response to this requirement, please provide answers to each of the following interrogatories eliciting factual information:

(1) What is the earliest publicly available date of the journal Dermatology in which the above Lin et al. article appeared? It is noted in this regard that front cover date of Application/Control Number: 10/600,006

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most journals are often much later than the actual delivery or receipt dates of the journals. Also, different receiving sources often report widely varying dates of receipt. This is why it's important to obtain the publisher's mail date of that particular issue, if available.

- (1a) Is there any other article on AXENOHL or a similar sliver product by applicant, applicant's assignee or predecessor assignees that was published prior to 10/9/1997?
- (2) What exactly was disclosed at the Third Asian Pacific Congress on Antisepsis and exactly when was that disclosure made and to whom?
- (2a) What printed matter regarding AXENOHL or a similar silver product by applicant, applicant's assignee or predecessor assignees, in printed form or otherwise, was handed out, distributed or made available at the Third Asian Pacific Congress on Antisepsis or at any other meeting, sales or marketing event, conference, or any other occasion prior to 10/9/1997?
- (2b) Was there any "on sale," offer for sale or other commercial activity regarding AXENOHL or a similar silver product by applicant, applicant's assignee or predecessor assignees at the Third Asian Pacific Congress or at any other meeting, sales or marketing event, conference, or any other occasion prior to 10/9/1997? Even if any such "on sale," offer for sale or other commercial activity took place outside of the United States, please provide information as to whether such activity was communicated to parties in the United States prior to 10/9/1997.

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(2c) At least the Lin et al. article is evidence of public use of AXENOHL by "another," which appears to have occurred no later than 1/24/1997 to 1/26/1997. What was the exact content or makeup of AXENOHL at that time, including any pre-mixes, concentrates or diluted forms? Also, since Lin et al. are based in Pittsburgh, PA, it is assumed that their public use occurred in the United States as well as Sydney, Australia. Please provide all information pertaining to the use of AXENOHL by Lin et al., including geographical location(s).

- (2d) Was there disclosure of how to make AXENOHL or a similar silver product by applicant, applicant's assignee or predecessor assignees at the Third Asian Pacific Congress on Antisepsis or any other meeting, sales or marketing event, conference or any other occasion prior to 10/9/1997?
- (3) Unrelated to the public use issue, supra, applicant submitted what appears to be an European Opposition communication dated 9/4/2008 regarding EP 1,041,879. This document is in German so the undersigned Examiner cannot fully understand its contents. If applicant has an English translation of this document, it should be submitted.

This requirement is subject to the provisions of 37 CFR 1.134, 1.135 and 1.136 and has a shortened statutory period of 2 months. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is (571)272-0620.

The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE. Johann Richter, can be reached on (571)272-0646.

The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/John Pak/

Primary Examiner, Art Unit 1616

/Johann R. Richter/ Supervisory Patent Examiner, Art Unit 1616